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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,831	12/21/2001	Paul Richard Vaughan	Q-67867	4805

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/023,831

Applicant(s)

VAUGHAN ET AL.

Examiner

Daniel M. Sullivan

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 28 March 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 31-35.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.


DAVID GUZO
PRIMARY EXAMINER

Continuation of 3. NOTE: Claims have been amended to limit the claimed hydroxylated triple helical protein to being a "synthetic recombinant" protein. As the protein previously examined was not limited to being a "synthetic recombinant" protein, examination of the amended claims would require a new search and further consideration of the art of record..

Continuation of 11. does NOT place the application in condition for allowance because: Applicant traverses the rejection of claims 31-33 and 35 under 35 USC §112, first paragraph, as lacking enablement for the full scope of the claimed subject matter on the grounds that the specification makes clear that the hydroxylated triple helical protein of the invention is capable of being used in applications other than therapeutic applications. In support of this, Applicant cites teachings from the specification indicating that the proteins "can include exogenous biologically active domains to provide additional protein function and other characteristic" and "the product-encoding nucleotide sequences may include a sequence(s) encoding a secretion signal". Applicant also cites Examples 7, which demonstrates synthesis of a hydroxylated triple helical protein wherein a Flag epitope is linked to a "SYN-C3" triple helical forming sequence. Applicant urges that the Flag epitope allows for easy separation of the hydroxylated triple helical protein through immunochromatography and concludes that since the claims are not limited to a therapeutic application, it is clear that the claims are enabled by the present specification. These arguments have been fully considered but are not deemed persuasive. As discussed in the Office Action mailed 26 January 2004, "with regard to using the claimed polypeptides, the specification teaches that the products may be used in a wide range of applications including bioimplant production, soft and hard tissue augmentation, wound/burn dressing, sphincter augmentation for urinary incontinence and gastric reflux, periodontal disease, vascular grafts, drug delivery systems, cell delivery systems for natural factors and as conduits in nerve regeneration" (paragraph bridging pages 4-5). The teachings cited by applicant merely contemplate ways in which the claimed polypeptide can be modified or isolated. They are not teachings of how to use the polypeptide so modified or isolated. As discussed in previous Office Actions, the only uses contemplated in the specification for the claimed polypeptide are therapeutic and, for reasons of record, the disclosure does not enable polypeptides for therapeutic use beyond the scope of hydroxylated triple helical proteins that are collagens.

Applicant traverses the rejection of claims 31-33 as anticipated by Fields et al., claims 31-35 as anticipated by St Pierre et al. and claims 31-32 as anticipated by any one of the identified Swiss-Prot database entries on the grounds that the art does not teach a synthetic recombinant protein. Applicant's arguments are predicted on the proposed amendments, which have not been entered in view of the fact that examination of the amended claims would require a new search and further consideration. Therefore, Applicant's arguments are moot.

With regard to the rejection of claims 31-35 under 35 USC §112, first paragraph as containing new matter, Applicant's argues persuasively that the application as filed contains adequate support for the limitation of (GlyXY)_n to n=2 to 50. However, Applicant's arguments are not deemed persuasive regarding support for the proviso "at least one of m and o is 1". In support of the proviso, applicant cites a teaching at page 2, lines 4-9, stating that the synthetic collagen "may include, for example, exogenous biologically active domains", which applicant asserts provides support for the requirement that at least one of "l", "m", "n" or "o" is 1. Applicant also points to a teaching at page 7, lines 12-13, that states, "triple helical proteins may include non-collagenous, non-triple helical domains at the amino and/or carboxy terminal ends or ELSEWARE" (emphasis added in Applicant's remarks) and a teaching at page 8, lines 17-30, which refers to the possibility of polypeptide domains being A, B, C and/or D. Applicant urges that these teachings provide a blaze marks to m or n being 1 or both m and n being 1. These argument is not persuasive because a statement that the protein can comprise embodiments wherein "m" and/or "o" are 1 does not support the requirement that if "m" is 0, "o" must be 1 and if "o" is 0, "m" must be 1 as the claims are limited by the proviso. As stated in the previous Office Action, "the original disclosure explicitly states that the values for m and o are 'selected independently'. In contrast, in the amended claim, the value assigned to m is dependent upon the value of o (i.e., if o is 0 m cannot be 0) and vice versa. Thus, the limitation of the claimed subject matter to exclude a subset of embodiments wherein both m and o are zero is neither explicitly nor implicitly supported by the originally filed disclosure." Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims stand rejected for reasons of record..

Continuation of 13. Other: Applicant's filing of a proper statement in accordance with Rule 1.821 is acknowledged..